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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/845,597 | 04/30/2001 | Antoni P. Tomsia | IB-1627 | 3236 |
| 8076 7590 10/12/2010 LAWRENCE BERKELEY NATIONAL LABORATORY Technology Transfer & Intellectual Property Managem One Cyclotron Road MS 56A-120 BERKELEY, CA 94720 | | | | |
| EXAMINER | | | | |
| CHIRISS, JENNIFER A | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1786 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/845,597

Applicant(s)

TOMSIA ET AL.

Examiner

JENNIFER A. CHRISS

Art Unit

1786

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 8 - 12, 20 - 28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 8 - 12, 20 - 28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/ISA-63)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. The Applicant's Remarks and Declaration under 37 CFR 1.132, filed September 29, 2010, have been entered and have been carefully considered. Claims 1, 5, 8 – 12, 20 – 28 and 30 are pending. In view of Applicant's argument that the December 1, 1998 presentation does not constitute a "printed publication" as the presentation of the material during a 15 minute time period would be transient, the Examiner has withdrawn the 35 USC 102(b) rejection over the paper entitled "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" *presented at the MRS 1998 Fall Meeting on December 1, 1998*. It should be noted that Applicant has provided no indication that the Applicant provided a copy of the slides to the attendees which could be considered a "printed publication", therefore, the Examiner is under the presumption that only a slide presentation was shown. For these reasons, the Examiner has not maintained this rejection. However, the other remaining rejections have been maintained for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. Claims 1, 8 – 11 and 20 – 28 remain rejected under 35 U.S.C. 102(b) as being anticipated by the paper entitled "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" available via Lawrence Berkeley National Laboratory with a

Art Unit: 1786

publication date of December 1, 1998.

The paper discusses coating a titanium-based alloy (Ti6Al4V) substrate with glass (page 349 or page 2 of 6) having the following compositions:

Table I Composition and main properties of the synthesized glasses

| | Composition (wt%) | | | | | | α | Ts |
|------|-------------------|-------------------|------|------|-------------------------------|------------------|--------------------------------------|-----|
| | SiO ₂ | Na ₂ O | CaO | MgO | P ₂ O ₅ | K ₂ O | (10 ⁻⁶ °C ⁻¹) | |
| 6P50 | 49.8 | 15.5 | 15.6 | 8.9 | 6.0 | 4.2 | 12.2 | 560 |
| 6P53 | 52.6 | 10.4 | 18.0 | 10.2 | 6.0 | 2.8 | 11.5 | 608 |
| 6P55 | 54.5 | 12.0 | 15.0 | 8.5 | 6.0 | 4.0 | 11.0 | 602 |
| 6P57 | 56.5 | 11.0 | 15.0 | 8.5 | 6.0 | 3.0 | 10.8 | 609 |
| 6P61 | 61.1 | 10.3 | 12.6 | 7.2 | 6.0 | 2.8 | 10.2 | 624 |
| 6P68 | 67.7 | 8.3 | 10.1 | 5.7 | 6.0 | 2.2 | 8.8 | 644 |

 α = Coefficient of thermal expansion (measured between 200 and 400°C)

Ts = Softening point

The paper also discusses bi-layered coatings (page 350 or page 3 of 6) as shown below:

Table II Multilayered glass coatings results

| Glass layers | Thickness (μ m) | Firing T (°C) | Coating results |
|----------------|----------------------|---------------|-----------------|
| 6P68/6P55 | 30/20 | 840 | Cracked |
| 6P61/6P55 | 30/20 | 820 | Good |
| 6P57/6P53 | 30/20 | 800 | Good |
| 6P57/6P50 | 30/20 | 800 | Cracked |
| 6P57/6P53/6P50 | 30/10/10 | 800 | Cracked |
| 6P57/(6P57+HA) | 30/20* | 800 | Good |

*HA: 6P57 = 50 wt%

The paper notes that depositing a glass-HA mixture as a layer on top of a glass that gives good adhesion to the metal (page 351 or page 3 of 6). It should be noted that claim 1 requires "up to 50 wt% of Ha particles". It is the position of the examiner that "up to" includes zero so the HA particles are optional and a reading of the present Specification indicates that this position is accurate. The glass composition of 6P50, 6P53, 6P55, 6P57 and 6P61 all anticipate the claimed glass composition of claim 1. The multilayered glass coating combination of 6P61/6P55 anticipates the layers of claim 9. The multilayered glass coating combination of 6P57/6P50 anticipates the layers of claim 10. The multilayered glass coating combination of 6P57/(6P57+HA) anticipates the layers of claims 11, 20 – 21, 23, 25 and 27. The paper notes that the coating operation can be repeated as many times as the desired number of layers (page 349 or page 2 of 6) which implies that more coating glass layers than two can be present resulting in Applicant's claimed "first intermediate layer" and "second intermediate layer". It should be noted that the term "about" in the claims is interpreted as +/- 5wt%.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5, 12 and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the paper entitled "A multilayer approach to fabricate bioactive glass

coatings on Ti alloys" available via Lawrence Berkeley National Laboratory with a publication date of December 1, 1998 in view of the article entitled "Novel Bioactive Functionally Graded Coatings on Ti6Al4V" by Gomez-Vega et al published March 1, 2000.

The paper and presentation entitled "A multilayer approach to fabricate bioactive coatings on Ti alloys" teach the claimed invention above but fail to disclose that the first layer, first intermediate layer and the second intermediate layers have a HA gradient as required by claim 5 and SiO₂ gradient as required by claim 30, where the concentration in the first layer is the lowest, the highest in the second intermediate layer with the first intermediate layer having a concentration between the other two.

The article entitled "Novel Bioactive Functionally Graded Coatings on Ti6Al4V" discusses graded bioactive glass coatings (paragraph 2, page 1). The article indicates that layers of glass with different compositions and mixtures of glass and HA were sequentially deposited on the metal and fast-fired under the conditions that provide optimum adhesion for glass in contact with the alloy (page 3, paragraph 2). The article notes the use of step-wise variations of the glass components through each layer of the coating. The article indicates that by creating a SiO₂ gradient among the layers the adjacent layers can infiltrate due to the different softening points. The graded coatings reduce thermal stresses, enhance coating stability and have excellent adhesion to the metal layer (page 3, paragraphs 1 - 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a SiO₂ or an HA gradient in the first layer, first intermediate

layer and the second intermediate coating layers as suggested by the article entitled "Novel Bioactive Functionally Graded Coatings on Ti6Al4V" in the composite of "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" motivated by the desire to create a Ti-based coated alloy having reduced thermal stress, enhanced coating stability and excellent adhesion to the metal layer.

As to claim 12, Applicant requires that the first layer, first intermediate layer and the second intermediate layers have a specific glass composition. It should be noted that this composition is the composition described by "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" as 6P61. Furthermore, the article teaches using up to 50% by weight of HA particles in the top layer (page 351 or page 3 of 6). Additionally, the article notes that the coating operation can be repeated as many times as the desired number of layers (page 349 or page 2 of 6). As the secondary reference article, "Novel Bioactive Functionally Graded Coatings on Ti6Al4V", note that multiple layers allows the ability to make graded coating to reduce thermal stresses, enhance coating stability and provide excellent adhesion to the metal layer, it would have been obvious to create a composite with three coating layers each having the same disclosed glass composition with the first layer having 50% by weight of HA particles as all of the claimed elements are known and one skilled in the art could have combined the elements as claimed by known methods with no change to their respective functions and the combination would have yielded the predictable result of enhanced coating stability, reduced thermal stress and excellent adhesion of layers.

Response to Arguments and Declarations under 37 CFR 1.132

6. Applicant's arguments and Declaration filed September 29, 2010 have been fully considered but they are not persuasive.

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7. In a Declaration pursuant to 37 CFR 1.132, Applicant indicates that the earliest possible date that the library first made the paper entitled "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" available to the public is October 9, 2001 which was by putting the paper online. However, as noted in the previous rejection, there are multiple citations of the paper clearly indicating that the **publication date** is December 1, 1998. Applicant has not provided any evidence to account for this discrepancy only arguments. Although the document may have only been available to the public *online* on October 9, 2001, the document need not be made available online to be considered within the definition of published. It is the position of the Office that the document was disseminated earlier in some sort of print form, specifically, on its publication date of December 1, 1998 until evidence has been provided to the contrary. The rejections over the paper have been maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is (571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Chriss/
Primary Examiner, Art Unit 1786

/J. A. C./
Primary Examiner, Art Unit 1786